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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,965

09/14/2005

Tim Bowden

1510-1102

7978

466 7590 10/30/2007  
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EXAMINER

DICKINSON, PAUL W

ART UNIT

PAPER NUMBER

4173

MAIL DATE

DELIVERY MODE

10/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/526,965

Applicant(s)

BOWDEN ET AL.

Examiner

Paul W. Dickinson

Art Unit

4173

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 8-9, 13-17 and 21-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-12 and 18 is/are rejected.
- 7) ☒ Claim(s) 19 and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

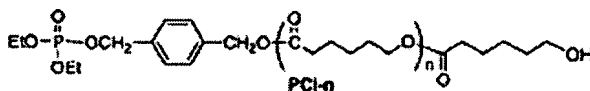
### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 5/18/2007.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION*****Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-12 and 18-28 in the reply filed on 9/24/2007 is acknowledged. Applicant's species election with traverse of phosphatidyl choline as the terminal functional group and a polyester that is polymerized from trimethylene carbonate is also acknowledged.

The traversal is on the ground that the special technical feature of Groups I-III is the polymeric material. This is not found persuasive because the polymeric material, as defined in Instant Claim 1, is not novel. The Examiner cites Kim et al (Kim et al, Synthesis of Phosphate End-Functional Polymer and Application to Thermally Latent Polymeric Initiators, Journal of Polymer Science: Part A: Polymer Chemistry, 2001, 39, 3832-3840) which discloses a polymer compound comprising at least one biodegradable polyester having a terminal functional group based on hydrophilic moieties of phospholipids. Specifically, the polyester is poly( $\epsilon$ -caprolactone) and the terminal functional group is O-p-(hydroxymethyl)benzyl O,O-diethyl phosphate (see abstract; p 3835, col 1, bridging paragraph to col 2, last paragraph; Schemes 1-2; Figure 1):



The polymeric material of the instant application therefore cannot be properly considered a special technical feature.

Applicant traverses the species election requirement for the terminal functional group on the ground that there is no undue search burden. This is not found persuasive. There is no limiting definition in the specification that the functional groups are based on the polar head groups found in phospholipids. The phrase "functional groups based on hydrophilic moieties of phospholipids" in Instant Claim 1 reasonably encompasses a wide range of compounds/fragments (see below) each having different chemical structures and behaviors. It is not anticipated that the prior art applicable to one species would likely be applicable to another species.

Applicant traverses the species election requirement for the polyester on the ground that there is no undue search burden. This is not found persuasive. The polyesters of the instant invention can be made by other routes besides ring opening polymerization. For example, polyglycolide can be made by polycondensation of glycolic acid (see US 20040230026, ¶ 3-7). The polyesters of the instant invention have different reaction chemistry, and it is not anticipated that the prior art applicable to one species would likely be applicable to another species.

Applicant is reminded that upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant states in the reply filed on 9/24/2007 that the elected species reads on claims 1-7 and 10-22. The elected species does not, however, properly read on this set of claims, but rather on the following: Claims 1-7, 10-12, 18-20.

Claims 8-9, 13-17, 21-28 are hereby withdrawn. Claims 1-7, 10-12, 18-20 are currently under consideration.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "functional group based on hydrophilic moieties of phospholipids" in Claim 1 is vague and indefinite. It is unclear what compounds/fragments "hydrophilic moieties of phospholipids" encompasses. There is no limiting definition of this term in the specification. Furthermore, it is unclear how far a functional group based on said hydrophilic moieties can deviate from the parent compound without it being so far removed therefrom as to be a completely different compound.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-7, and 10-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Lucke et al (Lucke et al, Peptide Acylation by Poly(alpha-Hydroxy Esters, Pharmaceutical Research, 2002, 19(2), 175-181) discloses poly(D,L-lactic acid) and poly(lactic-co-glycolic acid) (see p 175, col 2, last paragraph to p 176, col 1, first paragraph). Both polymers are terminated by carboxylic acid and have a MW of 17,000 g/mol (see p 175, col 2, last paragraph; Figures 1 and 6).

Claims 2 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hecht et al (Hecht et al, Porphyrin Core Star Polymers: Synthesis, Modification, and Implication for Site Isolation, *J. Am. Chem. Soc.*, 1999, 121, 9239-9240). Hecht et al disclose a polymer compound comprising a plurality of polyester polymers emanating from a central core so as to form a dendrimer, each polyester polymer being terminated

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by a coumarin (referred to as **5b**) (see col 2, first full paragraph; Scheme 2). The Examiner is interpreting "a terminal functional group based on hydrophilic moieties of phospholipids" in Instant Claim 1 to encompass coumarin. The Examiner is interpreting "an essentially spherical particle" in Instant Claim 12 to encompass compound **5b** disclosed by Hecht et al.

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Burt et al (Burt et al, Development of copolymers of poly(D,L-lactide) and methoxypolyethylene glycol as micellar carriers of paclitaxel, Colloids and Surfaces B: Biointerfaces, 1999, 16, 161-171). Burt et al discloses a diblock copolymer containing one block of poly(D,L-lactide) and one block of methoxypolyethylene glycol in the shape of micelles (see abstract; p 163, col 1, last paragraph to p 164, col 1, last paragraph; p 170, col 2, first full paragraph to last paragraph). The Examiner is interpreting "a terminal functional group based on hydrophilic moieties of phospholipids" in Instant Claim 1 to encompass methoxypolyethylene glycol.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/56802. '802 discloses a hyperbranched dendritic polyester wherein the dendritic polyester is terminated by functional groups (see abstract; p 1, first paragraph; p 4, second and third paragraphs). While there are no specific examples disclosed, the following functional groups are contemplated: carboxylic acid, carboxylate (p 4, second paragraph; Claim 18), and various organic acids (see Claim 19). The Examiner is

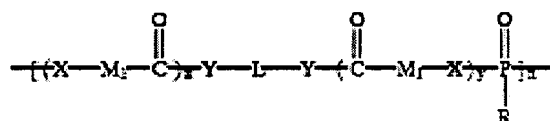


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interpreting "a terminal functional group based on hydrophilic moieties of phospholipids" in Instant Claim 1 to encompass these organic acids.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6166173 in view of Kim et al (see above). '173 discloses a method comprising (i) reacting a cyclic ester monomer and an alcohol in the presence of a catalyst to provide a ring opened polymer having an –OH terminated end, (ii) reacting the –OH terminal end of the obtained polymer with a phosphorodihalidate to provide a polymer having a phosphate terminated polymer, and (iii) reacting said polymer with chloroform to obtain a polymer. (see col 4, ln 33 to col 5, ln 25; Example 1). The method in the example disclosed by '173 produces a copolymer of L-lactide and ethyl phosphate. '173 fails to disclose an example wherein the product polymer has a functionalized end. A product polymer with a functionalized end is, however, contemplated by the specification.

Specifically, the following formula is provided:



wherein the ratio of n to (x or y) is about 1:200 (see col 3, ln 45 to 55; col 4, ln 16-17).

Kim et al discloses the benefit of end functionalized cyclic esters. Specifically, introduction of functional groups into the polymer end provides a promising

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methodology of controlled macromolecular architectures (see p 3833, first paragraph; p 3839, first full paragraph).

In the pursuit of improved macromolecular architectures, one skilled in the art would be motivated to select the embodiment of the method disclosed by '173 wherein the product is a polymer with a functionalized end, with a reasonable expectation of success.

### ***Allowable Subject Matter***

Claims 19-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul W. Dickinson whose telephone number is 571-270-3499. The examiner can normally be reached on Mon-Thur 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul W Dickinson  
Examiner  
Art Unit 4173

October 24, 2007

*Ardin H. Marschel 10/28/07*  
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SUPERVISORY PATENT EXAMINER